more information about those therapies. PDUFA provides an important part of that, but it cannot do it all."

As work on renewing PDUFA moves forward, Enzi urged Congress to carefully rethink its commitment to FDA, suggesting higher and higher demands being placed on the agency's resources will require more than the user fees from drug manufacturers included in PDUFA to keep pace with rapid advances in medicine and technology.

"User fees were never intended to supplant appropriations – they were intended to supplement appropriated funds. The industry has committed ever-increasing amounts of money. The agency has committed to meet ever more ambitious performance goals," he said. "Now congress needs to demonstrate its commitment to drug safety by giving FDA the tools it needs."

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Hearing Statement
Michael B. Enzi
"Drug User Fees: Enhancing Patient Access and Drug Safety"

"Thank you, Mr. Chairman, for holding this important hearing. We are here today to talk about reauthorizing the Prescription Drug User Fee program, or more widely referred to as PDUFA.

The Prescription Drug User Fee program is a tried and tested program. It is a successful partnership between industry and the Food and Drug Administration (FDA). FDA must meet rigorous timeframes for the review of important new drug therapies for patients. Through fees on drug manufacturers, PDUFA has enabled the partners to meet the deadlines, while still preserving patient safety. However, where we are today is not where we need to be tomorrow.

We are not a "rear view mirror" country. We are a pedal to the metal country – always optimistic and looking to the future – always looking at how to make things better. While the PDUFA program is a system the public can always count on, it can and should be improved.

In the early 90's, AIDS and Cancer advocates picketed in front of the Parklawn Building at the FDA demanding faster access to life saving drugs. New therapies at that time were being approved in other countries, and there was "drug lag" of sometimes years before they were approved in the United States. Americans were dying because of this "drug lag."

(More . . . more)

While the "drug lag" has now shifted to other countries and most drugs are now approved first in the United States, patients still want safe drugs but don't want to die waiting for them. Increasing access to life saving drugs initially drove the goals of the drug user fee program resulting in ever faster approvals. This has had a tremendous effect on the number of available new therapies, particularly for conditions such as AIDS and cancer.

We are now at a point at which approvals are probably as fast as they can or should be, and attention is turning back to safety issues. A drug that is never approved is completely safe. But this is not a tradeoff that Americans are willing to make. So now our challenge is getting back to basics and moving towards a model in which access includes an increased focus on activities directed toward identifying and managing safety issues. We can and should achieve both goals – access and safety.

This better approach entails rapid pre-market evaluation of innovative new therapies combined with tracking and evaluating safety issues in the post-market setting over the entire life span of the product. An example is the many drugs which have turned fatal diseases into chronic conditions. The safety issues associated with a drug that is taken for years are different than one that is taken for a week. On the one hand, patients with a life threatening disease may be more willing to take a drug with risks, but if they may be on that drug for years, they also want to know more about side affects and weigh safety and access differently.

I believe the FDA needs new authorities to acquire and evaluate safety information and act on it promptly. Senator Kennedy and I have introduced legislation to grant the agency those new authorities. Our proposal creates robust systems to collect, assess, evaluate, and respond quickly to safety information.

In addition to the new authorities, I believe we need to examine the persistence of some of the very conditions that led to the enactment of PDUFA. The user fees were never intended to supplant appropriations – they were intended to supplement appropriated funds. The industry has committed ever-increasing amounts of money. The agency has committed to meet ever more ambitious performance goals. As part of the reauthorization of this important program, we must ask ourselves what sort of commitment we the Congress need to make to this agency. We must review our financial commitment to the program and be open to rethinking what we have agreed to do in light of the evidence that funding is currently not sufficient to do all we require of FDA."

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